Lined Balloon Mounted Stent (detailed description):

This invention is about to mount a non reactive inflatable tissue on an appropriate size intravascular stent to control the flow distally. This created stent is then placed on the intended vessel per catheter. This tissue can be put in different designs:

1. A tire in a wheel with a central opening.
2. In the form of successive openings of different sizes to allow for future change in the size of the stenosis imposed to the circulation by interventions e.g. balloon catheters to remove one of the narrowings for example.
3. Crescentic or boggy masses of enclosed tissue that can be compressed later on e.g. by a balloon to modify the gradient across the stenosis produced e.g. pulmonary artery.
4. A design similar to naturally occurring stenotic valves.
5. A stenotic absorbable material to allow for natural progressive dilatation.
6. A stenotic material that swells with time to allow for progressive narrowing.

Figure 1 and 2 demonstrate a sketch of one version of items 1 and 4.

All these designs can be inflated or deflated to control their size during the procedure and sometimes later as well. The inflation can be done by carbon dioxide, air or even different fluids e.g. normal saline. The addition of the ability to compress the narrowed segment later on by dilating balloons is again feasible as well.

This could replace state of the art procedures e.g. the pulmonary artery band that we know and are using now.

For this purpose the metallic dilatable stents in common use in cardiology practice can be prepared to hold the balloon inside it. The balloon material that can be used is similar to the one used in valvotomy balloons in our current practice, however the essential requirement is only inflatability and non reactivity.

As this procedure is expected to be done in the catheterization laboratory, I believe it would be executed with much less mortality, morbidity and expense as compared to its surgical counterpart. I expect it thus to revolutionize the practice. Because the ability to perform a per catheter band without mortality will definitely make surgical corrections of some simple as well complicated cardiac lesions not needed or at least deferrable to the time where they could be done with less mortality. If we combine this by the ability to control the pressure gradient during insertion (e.g. doing echo or direct measurement in the cath and ascertaining the hemodynamic consequences directly). Again,

the ability to reduce or increase the pressure gradient at the same setting or at later settings. For more complex lesion, it can be done as a permanent palliation or in preparation for future palliation.
I suggest the name of Lotfy's stent for the stent that will be designed for this purpose.

The previous state of the art:

To achieve control over the blood flow inside the vessels a surgical procedure is undertaken (with its inherent costs, risks) to band the vessel from outside. Different systems had been devised for this but they were all applied from outside the vessel.

Problems in the previous state of the art:

1. High cost of the surgery, with inherent risks and problems associated with the throracic surgeries.
2. Sometimes the condition of the patient (e.g. a sick baby) is not suitable for the operation despite its urgency.
3. The inability to change the degree of the band once the operation is over except with another operation with again higher risks.
4. Fibrosis and distortion produced during and after the surgery would make future operations in the area involved more difficult.

What is new about the invention ?

1. Achieve the same result as the surgical intervention.
2. Avoid the risk and complications of surgery and reoperation.
3. The ability to change the degree of narrowing produced during and after the catheter procedure.

The procedure of pulmonary artery banding and related procedures was never reported in the literature to be done intravascularly.

How can it be used ?

A selected company producing the common use intravascular stent will be chosen after agreement with the inventor to upgrade some of its stents with the new designs and linings I suggested.